09-14-07

AF

UNITED STATES PATENT AND TRADEMARK OFFICE
BEFORE THE BOARD OF PATENT APPEALS AND INTERFERENCES
(CASE NO. MBHB00-203)

In Re Application of:	)
	)
Ruderman, et al	)
	)
Serial No.: 09,534,946	)
	)
Filed: March 24, 2000	)
	)
Title: CARDIOVASCULAR	)
HEALTHCARE MANAGEMENT	)
SYSTEM AND METHOD	)

TRANSMITTAL LETTER

MAIL STOP: APPEAL BRIEF - PATENTS
Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450

In regard to the above identified application:

1. We are transmitting herewith the attached:

2. a. Reply to Examiner's Answer; and
   b. Postcard.

3. No fee is required.

4. Please charge any additional fees or credit overpayment to Deposit Account No.13-2490.

Respectfully submitted,

McDONNELL BOEHNEN
HULBERT & BERGHOFF

John J. McDonnell
Reg. No. 26,949

McDONNELL BOEHNEN
HULBERT & BERGHOFF LLP
300 SOUTH WACKER DRIVE
CHICAGO, ILLINOIS 60606

CERTIFICATE OF MAILING UNDER 37 CFR § 1.8: The undersigned hereby certifies that this Transmittal Letter and the papers, as described in paragraph 1 hereinabove, are being deposited with the United States Postal Service with sufficient postage as U.S. Express Mail No.EV839381117US addressed to: Mail Stop Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450 on this 13 day of September 2007.

BEFORE THE BOARD OF PATENT APPEALS AND INTERFERENCES

Application Number: 09/534,946
Filing Date: March 24, 2000
Appellant(s): RUDERMAN, et al

John J. McDonnell
For Appellant

REPLY TO EXAMINER'S ANSWER

This Reply is in response to the Examiner's Answer mailed on August 8, 2007.

35 U.S.C. § 103(a) provides:

> A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title [35 USC 102], if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

The factual inquiries set forth in *Graham v. John Deere Co.,* 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

Claim 38 reads as follows:

> 38. A cardiovascular healthcare management system comprising:
>
> (a) an infomediary site having databases for cardiovascular healthcare management which includes a database of test results of concentration of subclasses of LDL particles and subclasses of HDL particles from at least 900 cardiovascular patients;
>
> (b) a data entry interface for receiving patient personal data and test results for concentration of subclasses of LDL particles and subclasses of HDL particles storing the data and results in the infomediary site databases;
>
> (c) a diagnostic engine for analyzing patient test results for subclasses of LDL particles, subclasses of HDL particles data and identifying patients who do not have

hyperlipidemia based on total LDL cholesterol and total HDL cholesterol, but are in need of treatment; and

(d) wherein the subclasses of LDL particles and subclasses of HDL particles are levels determined by segmented gradient gel eletrophoresis and wherein the particle sub-classes include HDL 2b.

The Examiner takes the position that the combination of Levin, Otvos and Kraus renders claim 38 obvious under 35 U.S.C. § 103(a). Applicant respectfully disagrees.

Levin U.S. Patent 5,724,580

The Office Action acknowledged that Levin does not disclose a data base with LDL subclasses and HDL subclasses. Levin does not recognize the LDL subclass and HDL subclass analysis can identify patients that have apparently normal LDL and HDL total values, which the whole point of the invention. Applicant's healthcare management system achieves this important health care advancement which was not known to exist in the prior art nor was it predictable. The expanded data unpredictability revealed the claimed relationship. Such a data base does not exist in the art and the results derived from such a data base are not obvious because it could not be determined if the claimed result even existed until applicant collected and analyzed the data base. Such a retrospective look at applicant's results and specification can not be the basis for obviousness. If anything Levin teaches away from applicants invention in that it only considers total HDL and LDL in the data base. For example, figure 25A of Levin provides:

LIPID PROFILE

Our records do not include any data on the lipid levels of patient. Since lipids are a major modifiable risk factor for CAD and its complications, we recommend obtaining LDL, HDL and triglyceride levels before the patient's next ischemia monitoring with Monitor One STRx. If these values are currently known, please report them to us.

Applicants claim a system that determines cardiovascular disease where total HDL and total LDL are normal. Levin does not suggest LDL subclass and HDL subclass data base

and does not suggest the necessity of segmented gel electrophoresis HDL 2b data. There is no suggestion to combine Levin with information found in Otvos and Krause.

Otvos U.S. Patent 6,576,471

Otvos describes determining some HDL and LDL subclasses by NMR. The limitation of NMR are described in the Shewmake Declaration in the Response of December 27, 2004 (Exhibit 5). **The entire Shewmake Declaration is incorporated herein by reference. In particular see paragraphs A, B and C.**

Thus NMR is not capable of accurately determining key subclasses such as HDL 2b. Otvos does not recognize the possibility of identifying patients with normal LDL and HDL who need treatment and the NMR technique is incapable of doing so. We note the applicant's claims are limited to gradient gel electrophoresis data for respective HDL and LDL subclass data and HDL 2b is a required subclass.

Contrary to the Examiner's position, Otvos does not suggest the necessity of HDL2b faction in the database and does not provide a means of obtaining HDL2b data

The Shewmake Declaration paragraph E concludes:

> E. The Otvos NMR technology described in the 6,576,471 patent is not capable of identifying those patients with normal HDL and LDL who are in need of treatment as described and claimed in this application.

Krauss U.S. Patent 5,925,229

Krauss only describes the use of segmented gel electrophoresis to determine some LDL subclasses and does not describe the separation of HDL subclass. Krauss does not describe a data base of LDL subclasses or HDL subclasses. Krauss does not describe any HDL subclasses, much less the HDL 2b subclass present in the data base of the claimed health care management system.

This is contrary to the Examiner's statement on page 8 of the Examiner's Answer.

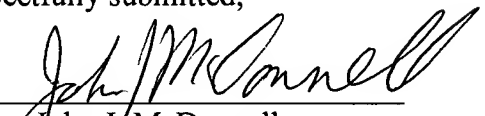
> Krauss discloses using segmented gradient gel electrophoresis to determine the subclasses of LDL particles and HDL particles (col 1 line 15 to col 2, line 47, col 14 line 61 to col 16 line 22).

Furthermore, applicants' Background of Invention Section does not reveal the HDL2b subclass and its role in identifying patients with normal HDL and LDL values who need treatment.

> The art describes cardiovascular risk factors such as age, smoking, weight, family history, blood pressure, lipid profiles including low density lipoprotein (LDL) and high density lipoprotein (HDL) and subclasses (fractions) of LDL and HDL. Methods for measuring these factors and relating them to patient treatment are also known. Generally physicians assess a patient's risk factors, make a diagnosis based on test results and symptoms and manage patient treatment through drugs, exercise, diet and a variety of surgical techniques. Instructions are generally given directly to the patient by the physician. Patient compliance generally involves interview in follow-up office visits.

It is respectfully submitted that the combining of the above references to render obvious claim 38 and claims dependent on claim 38 is improper. There simply is no teaching or suggestion of HDL2b data (determined segments gel electrophoresis) as necessary for identifying patients with normal LDL and HDL who need treatment.

Respectfully submitted,

By: 

John J. McDonnell
Reg. No. 26,949

McDonnell Boehnen
Hulbert & Berghoff LLP
300 S. Wacker Drive
Chicago, IL 60606